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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,171	09/09/2003	Roddi James Simpson	0100/0162	1010

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EXAMINER

HAN, MARK K

ART UNIT PAPER NUMBER

3767

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/657,171

Applicant(s)

SIMPSON ET AL

Examiner

Mark K. Han

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-16 and 18-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Invention II, Species I in the reply filed on 23 May 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 2-9 and 17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention/species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 23 May 2005.
3. Claim 10 link(s) several species. The election of species requirement among the linked species is subject to the nonallowance of the linking claim(s), claim 10. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked species shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction/election

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of species requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,599,318 to Sweeney et al. (hereinafter “Sweeney”).

Sweeney discloses a unitary molded syringe having a syringe barrel 162, a needle hub 128, a collar reception mechanism 204, a collar 132 having a needle protection housing 135, a slot (unnumbered), one locking portion (unnumbered) and another locking portion (unnumbered). See Figure 18.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sweeney.

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Sweeney discloses the claimed invention as shown above. Sweeney discloses the use of at least one protrusion 203 to engage the collar to the syringe. Sweeney, however, does not expressly discuss the use of a plurality of flanges. It is considered that a plurality of flanges is a functionally equivalent alternative to the at least one protrusion of Sweeney that is well-known in the mechanical arts. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a plurality of flanges for the at least one protrusion of Sweeney since it was known in the art that a protrusion and a plurality of flanges are interchangeable.

6. Claims 11, 15, 18-20, 22, 23, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,643,219 to Burns in view of Sweeney.

In reference to claims 11, 15, 18-20, 23 and 26, Burns discloses a syringe 37 having a barrel, needle hub 20, collar reception mechanism 28, collar 48, needle protection housing 38, slot 46 having a channel, groove 28, collar having at least one protrusion 54, at least one locking portion 58 and another locking portion 30. See Figures 1-11. In reference to claims 15 and 23, it is assumed that the distal end of the syringe and the collar are at least substantially flush; otherwise, the sheath would not be able to hinge to cover the needle as required by the Burns invention.

Burns discloses the claimed invention as shown above. Burns, however, does not disclose that syringe barrel and the needle hub are integrally formed. Sweeney suggests an integrally formed hub and barrel. See Figure 18. It would have been obvious to one of ordinary skill in the art to modify the invention of Burns, by integrally molding the syringe barrel and needle hub, as suggested by Sweeney, in order to prevent the exchange of needles of different gauges, which may cause improper dosage of medicament to the patient.

In reference to claim 22, Burns and Sweeney disclose the use of at least one protrusion to engage the collar to the syringe. Burns and Sweeney, however, do not expressly discuss the use of a plurality of flanges. It is considered that a plurality of flanges is a functionally equivalent alternative to the at least one protrusion of Burns and Sweeney that is well-known in the mechanical arts. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a plurality of flanges for the at least one protrusion of Burns and Sweeney since it was known in the art that a protrusion and a plurality of flanges are interchangeable.

7. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sweeney in view of U.S. Patent No. 5,681,295 to Gyure et al. (hereinafter "Gyure").

Sweeney discloses the claimed invention as shown above. Sweeney, however, does not show a catch or a semicircular portion. Gyure, discloses a pivotable sheath having a catch 58 and a semicircular portion 69. See Figures 1-13. It would have been obvious to one of ordinary skill in the art to include a catch and semicircular portion, as suggested by Gyure, in the invention of Sweeney in order to secure the needle to the housing and to provide a platform for the user to provide sufficient torque to pivot the needle sheath to enclose the needle.

8. Claims 16, 21 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burns and Sweeney, as above, further in view of Gyure.

Burns and Sweeney disclose the claimed invention as shown above. Burns and Sweeney, however, do not show a catch or semicircular portion. Gyure, discloses a pivotable sheath having a catch 58 and a semicircular portion 69. See Figures 1-13. It would have been obvious to one of ordinary skill in the art to include a catch and semicircular portion, as suggested by

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Gyure, in the invention of Burns and Sweeney in order to secure the needle to the housing and to provide a platform for the user to provide sufficient torque to pivot the needle sheath to enclose the needle.

Response to Arguments

A. Zecha Declaration is insufficient.

The declaration of Frederick P. Zecha under 37 CFR 1.132 filed 13 December 2005 is insufficient to overcome the rejection of claims 11, 13-16 and 18-26 based upon 35 U.S.C. §103(a) as set forth in the last Office action because: The declaration falls short of establishing the invention's commercial success. Evidence of sales figures while part of the commercial success analysis is of little value in the absence of an adequate showing as to the reasons behind such sales. See Cable Elec. Products, Inc. v. Genmark, Inc., 770 F.2d 1015 (Fed. Cir. 1985). Moreover, such sales data must be placed in perspective by evidence demonstrating that the subject invention displaced prior art devices or surpassed the volume sales of prior art devices that applicant's market share increased significantly after introduction of the device. As for declarant's statements or opinion concerning the reasons behind such commercial success (i.e. the nexus between the merits of the claimed invention and the evidence of commercial success), the Examiner finds that declarant's statements are entitled to little, if any, weight. There is no evidence in the record establishing the declarant as an expert. Accordingly, declarant's opinions are of little probative value and fall short of establishing a connection between the objective evidence offered and the merits of the claimed invention.

B. Arguments to art rejections are moot.

Applicant's arguments with respect to claims 10-16 and 18-26 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark K. Han whose telephone number is 571-272-4958. The examiner can normally be reached on Monday to Friday, 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark K. Han
Patent Examiner
Art Unit 3767

mkh
March 13, 2006



MICHAEL J. HAYES
PRIMARY EXAMINER